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09/667,130	09/21/2000	John W. Barnwell	5986/17686-US5	8596

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New York, NY 10022

EXAMINER

DUFFY, PATRICIA ANN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/01/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/067,130

Applicant(s)

Barnwell

Examiner

Duffy

Group Art Unit

1045

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on Re: In re James of 9-21-00 + 5-24-02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 22 + 23 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 22 + 23 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

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### DETAILED ACTION

1. The preliminary amendment filed 9-21-00 has been entered into the specification. Claims 22 and 23 are pending and under examination.

#### *Priority*

2. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

#### *Drawings*

3. The drawings are objected to by the draftsman for the reasons set forth on the PTOL-892. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will NOT be held in abeyance.

#### *Specification*

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4. A substitute specification including any amendments and the claims is required pursuant to 37 CFR 1.125(a) because the submitted specification did not have proper top margins and as such there is missing text where holes have been punched to affix the specification to the file.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

6. The preliminary amendment filed 9-21-00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "EcoRI digest of purified ..... for 2 months." which is inserted at page 5, line 18 after "1989".

As previously set forth by the examiner in the parent application this constitutes new matter because: the Southern et al describes multiple hybridization conditions, none of which are referenced or defined as "stringent hybridization conditions". The specific hybridization conditions which applicants propose to insert into the specification are not defined as stringent hybridization conditions by Southern et al, as the specification states. The specification states that ""Stringent conditions" are as defined by Southern et al in *J.*

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*of Mol. Bio., 98:503* and as detailed in....". MPEP section 608.01(p) states that "Particular attention should be directed to the specific portions of the referenced document where the subject matter to be incorporated can be found." In the instant case Southern et al does not (a) define "stringent conditions" and (b) one would not be directed to select the particular specific conditions as compared to any of the other numerous examples of specific hybridization conditions set forth by Southern et al. The generic incorporation by reference does not direct one to the particular passage which applicants are relying on for support and attempt to introduce a particular set of hybridization conditions, selected from numerous examples in the Southern et al document, into the specification. It is noted and emphasized that "Particular attention should be directed to the specific portions of the referenced document where the subject matter to be incorporated can be found." and the specification does not point to the particular page or line of Southern et al as is required by this section of the MPEP. The generic improper incorporation on page 5, lines 15-18 of the specification does not point to that which is now attempted to be incorporated into the specification. It is emphasized that one would not be readily pointed to the section which applicants now attempt to incorporate. Southern et al does not define any "stringent hybridization conditions" and does not define the particular conditions applicants attempt to introduce as "stringent hybridization conditions". Thus, the attempt to amend the specification and claims is deemed new matter to the specification and the claims. Applicants have not addressed the section MPEP section 608.01(p) states that "Particular attention should be directed to the specific portions of the referenced document where the subject matter to be incorporated can be found". Applicants reliance on the "*Hawkins*" decisions and declaration were not persuasive because in the instant application no particular attention was drawn to the specific portions of the referenced

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document where the subject matter to be incorporated could be found as is specifically directed by the MPEP and Hawkins. Further, the "Hawkins declarations", filed during the prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit or declaration, the applicant should include a copy of the original affidavit or declaration filed in the parent application. Applicant indicates that the "Hawkins" decisions are controlling case law directly on point to this situation. The situation in Hawkins is distinguished from the instant case: the disclosure in Hawkins the specification specifically directed one skilled in the art to specific compounds and the methodology used to make them in the identified copending British Applications incorporated reference, in contrast, the instant case picks and chooses among a plethora of hybridization conditions, none of which are called or defined by Southern et al "stringent conditions". Such a selection among numerous alternatives is not supported by the Hawkins decisions argued by applicant. These arguments remain not persuasive because these particular conditions were neither specifically identified nor specifically referred to in the instant specification as originally filed. Applicant argued that the examiner misinterprets page 5, lines 15-19 as a definition by Southern et al and not an indication of stringent conditions as defined by applicant. Applicants' argued that they can be their own lexicographer and can define stringent conditions in any manner they set forth. This was not persuasive, the passage clearly indicates that ""Stringent conditions" are as defined by [emphasis added] Southern et al....". The operative word here is "by". Southern et al defines no "stringent conditions", nor does Southern et al refer to any particular set of conditions which are "stringent". Southern et al describes multiple examples of hybridization conditions (see for example page 507, lines 7-11, page 510, figure legend, page 510, Table 2, page 511, Figure 5,

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variation in temperatures of hybridization, page 511, Figure 6, variation in time of hybridization, page 515, figure legend). The passage of the specification fails to provide direct one skilled in the art to the specific hybridization conditions now inserted into the specification and claims. Incorporation by reference must particularly reference the specific teaching relied upon. At this point, the passage in the instant specification does not direct one skilled in the art to these particular conditions now recited. Applicant also argued that they need not claim all that is in the specification. This is not persuasive when relying upon an incorporation by reference for specific teachings. It is not clear which particular hybridization conditions were conceived by applicants at the time of filing and therefore it is highly relevant that the Southern et al reference discloses multiple hybridization conditions. The Hawkins decisions provides clear indication that the incorporation by reference must make it clear what information is being relied upon to complete the disclosure. In the instant case, it is not clear that which was conceived at the time of filing and that *particular information* in the document was to be referenced as opposed to the plethora of other hybridization conditions. The present case is different from the "Hawkins" decisions, different from *In re Voss*, 194 USPQ 144 (CCPA 1973) and *In re Fouche*, 169 USPQ 429 (CCPA 1971). In *In re Voss*, the court cited *In re de Seversky* 474 F.2d 671, 177 USPQ 144 (CCPA 1973), where the requirements for an incorporating references were clearly set forth. The incorporating statement must clearly identify the subject matter to be incorporated and where it is to be found. In the instant case these requirements are not met by the specification passage of page 5, lines 15-20. Since the entirety of the reference is cited, it is also unclear which portion(s) of the reference applicant rely upon or specifically where in the reference they are to be found.

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The subject matter to be incorporated cannot clearly be identified by a mere reference to the entirety of a citation.

Further, Applicants have argued that stringent conditions was a well-known and frequently used term in the art. This is not persuasive on its face because the art uses the terms not to precisely define a single set of conditions but is a generic term, with no precise indication of the conditions. A recitation of the term "stringent conditions" does not allow the skilled artisan to instantly envision a particular set of conditions. Stringent conditions are not art defined but are clearly relative and is not a single set of conditions (see for example the declaration of Dr. Crothers paragraph 8). Dr. Crothers declares that in his opinion that any of the conditions set forth in the Southern publication would be considered stringent hybridization conditions and that any of the disclosed conditions would have resulted in selection of hybrids. In contrast, Dr. Crothers declares that based on the examination of the experimental conditions in the Southern et al publication, stringent hybridization is a generic term that does not apply to any set of specific conditions "It is generally found that this temperature occurs about 20 degrees Celsius below the melting temperature of the hybrid duplex..." and as such stringent conditions are in fact therefore defined and characterized by the melting temperature of the hybrid duplex disclosed by Southern et al and not the instant SEQ ID NO:1. Declarant argues that all the conditions in Southern et al are in fact stringent because stringent hybridization is typically carried out at the temperature that maximizes the hybridization rate of the target duplex. There is no evidence that the target rate of the species disclosed in Southern et al is the same as SEQ ID NO:1. As indicated by Dr. Crothers, "It is generally found that this temperature occurs about 20 degrees Celsius below the melting temperature of the hybrid duplex...", however, there is no indication of the melting



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temperature of the instantly claimed hybrid duplex. Moreover, such a definition is necessarily a function of the hybrid duplex, because those that are less similar would have different melting temperatures and would therefore by definition have different "stringent conditions" based upon Dr. Crouthers declaration. Further, Dr. Crothers declares that stringent conditions are typically carried out at the temperature that maximizes the hybridization rate of the target duplex and Dr. Crothers et al indicates that Southern et al teach that 80 degrees Celsius in 6X SSC was maximal. Thus, how can declarant conclude that 65 degrees Celsius in 1X SSC was stringent when declarant also states that stringent conditions are "typically" carried out at the temperature that maximizes the hybridization rate of the target duplex. Clearly, the claimed rate is not the maximal rate as demonstrated by Southern et al. As such, it is unclear how Declarant can conclude that the recited conditions 65 degrees and 1X SSC are stringent when Southern et al does not describe 65 degrees as the maximal rate. It is clear that applicants which any of a variety of hybridization conditions to be considered stringent, when such selection of conditions is empirical in nature and not defined by the art. This is emphasized by Dr. Crouthers' declaration that states that the stringent conditions are essentially defined by melting temperature of the hybrid duplex and is typically carried out at the temperature that maximizes the hybridization rate. If one takes the position of Dr. Crouthers, then clearly 65 degrees does not meet the declarant's position of maximizes the hybridization rate. Dr. Crouthers, declaration emphasizes the examiners position that "stringent hybridization conditions" are not art defined and are not defined in Southern et al but are empirical in nature. Further, Dr. Crouthers states that a second important feature of stringent conditions is the importance of the was period at the hybridization temperature. It is noted that this declared important feature of "stringent hybridization" is not set

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forth in the claims and as such Applicants appear to pick and choose elements of hybridization protocols. Although, declarant states that the concept of stringency was familiar to those of skill in the art at the time, stringency as set forth by the Declarant is inconsistent for reasons set forth above, is empirical in nature and is not an art defined set of conditions. Declarant fails to set forth the melting temperature of the hybrid duplex as it relates to SEQ ID NO:1 and since stringency is related to the melting temperature of the hybrid duplex and the maximal rate of hybridization of the target duplex, it is additionally now unclear if the claimed conditions of Southern et al, meet the guidelines set forth by Declarant. The declaration of Dr. Crothers, supports the lack of specific definition in the art by referring to the incorporated hybridization conditions as dependent on melting temperature of the hybrid duplex, and "generally" or "typically", not "is" and "are". The specification specifically indicates that "'Stringent conditions" are as defined by [emphasis added] Southern et al....". Southern et al defines no "stringent conditions", nor does Southern et al refer to any particular set of conditions which are "stringent". Applicants indicate that the examiners interpretation of this passage is wooden. This is not so. If for example the passage said --- ineludible as defined by Webster's Ninth New Collegiate Dictionary --, one would go to the Webster's Ninth New Collegiate Dictionary to ascertain the meaning of this term. This is directly comparable to this case. One would have gone to Southern et al for definition of the stringent conditions. In the instant case Southern et al does not discuss "stringent conditions", "stringency" or define any conditions which are stringent. Applicants argue that they were not required to incorporate the conditions by Southern et al since the reference was well known to the art. This is irrelevant to the rejection at hand because applicants did generically incorporate by reference and are attempting to bring a set of specific conditions from the multiple

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conditions set forth in Southern et al. Southern et al sets forth *multiple hybridization conditions, none of which are defined as stringent*, and applicant has not identified by reasonable precision nor particularly pointed to with clarity those hybridization conditions which they or Southern et al considered "stringent". *In re Voss*, 194 USPQ 144 (CCPA 1973) and *In re Fouche*, 169 USPQ 429 (CCPA 1971) are particularly on point to this situation. The examiner disagrees with applicants for reasons already made of record and reiterated here, that applicants at the time of filing did not identify by reasonable precision nor particularly point to those sections of Southern et al with clarity.

Applicant's mere reference to Southern et al does not have the necessary specificity to particularly point out what from the multitude of conditions, applicants considered stringent as it relates to SEQ ID NO:1. Reference to specific conditions by page and line number is required for clarity and to identify with reasonable precision, that which is incorporated in a document that provides a variety of conditions none of which is defined as "stringent". Applicant's passage clearly lacks this clarity and precision. Applicant's argue that Southern et al is a "bible" and has been cited in Patents multiple times. As to the bible nature of the Southern et al reference, this is irrelevant to the rejection at hand, because Southern et al does not define stringent conditions. That the Southern et al reference has been cited many times in Patents is also irrelevant to the rejection at hand because each case is decided on its own merits. Applicant's assert that they cited Southern et al to illustrate examples of stringent conditions. The examiner maintains that this is not that which is specifically conveyed by this passage. Applicants argue that the person skilled in the art would have understood the meant of stringent hybridization conditions encompasses conditions like those disclosed in Southern et al. This is not on point, the issue is whether applicants pointed to the specific claimed and inserted

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conditions with reasonable precision and clarity to convey that the stringent conditions were 1X SSC at 65°. The examiner maintains the position that they were not.

The rejection is maintained.

***Information Disclosure Statement***

7. No information disclosure statement has been filed in this application.

***Double Patenting***

8. Claims 22 and 23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 22, 26 and 28 of copending Application No. 08/719,821. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species of full complements claimed in the copending application, would by definition hybridize to SEQ ID NO:1 and thus anticipate the instant genus claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 U.S.C. § 112***

9. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

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The recitation of "under hybridization conditions of 1X SSC at 65°C" is based on the amendment of the specification, which has support only from the incorporation of new matter into the specification as set forth in paragraph 3 above. As such it is not clear that applicant, had at the time of the invention, conceived of these particular hybridization conditions and therefore it is not clear that applicant was in possession of the claimed invention at the time of filing. Claims drawn to "hybridizing polynucleotide" is not equivalent to that which hybridizes under the specifically recited conditions in the claim. The fact that applicants could have claimed hybridizing polynucleotides, does not support hybridizing polynucleotides at a particular set of hybridization conditions as is now claimed. Applicant's arguments are not persuasive.

Applicant is required to cancel the new matter rejection in response to this office action.

10. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "stringent conditions" is vague and indefinite, since no particular conditions are defined in the specification. Thus, the term is found vague and indefinite because the particular assay conditions are not precisely defined in the specification. Stringency can be high, medium or low and is simply a relative term with no defined conditions and hybridizing DNA need not be identical to the encoding DNA. Further, according the Dr. Crothers declaration it can be defined based on the melting temperature of the hybrid duplex, and this melting temperature is not set forth in the specification. Thus, the metes and bounds of the hybridizing nucleic can not be ascertained.

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***Claim Rejections - 35 U.S.C. § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sigma Molecular biology Product Guide, 1991, pages 54-56).

Sigma et al teach isolated and purified oligo-d(pA) and oligo-d(pT) oligonucleotides. Each of the oligonucleotide products share 100% identity with at least residues 193-221 of SEQ ID NO:1. As such, these nucleic acids would hybridize under stringent conditions absent factual evidence to the contrary.

***Status of Claims***

13. No claims are allowed.

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

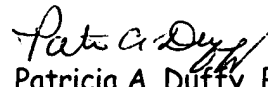
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

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Patricia A. Duffy, Ph.D.  
June 28, 2002

  
Patricia A. Duffy, Ph.D.  
Primary Examiner  
Group 1600